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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John Shigeura

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07/19/2006

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EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/908,994	SHIGEURA ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

2. *Specification*

3. The amendment filed 18 May 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: Newly added claims 21-28. A review of the disclosure fails to locate support of the new claims. While page 5 of the response of 18 May 2006 does state that support can be found throughout the specification and original claims, no one part or parts have been identified as support in any one newly added claim

4. Applicant is required to cancel the new matter in the reply to this Office Action.

5. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states at page 26:

All documents cited herein are incorporated herein by reference to the same extent as if
10 each individual document was specifically and individually indicated to be incorporated by
reference. While particular embodiments of the invention are described herein, it will be

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

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Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

As set forth In *Ex parte Raible*, 8 USPQ2d 1707, (BPAI, 1998)

The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree

* * *

We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144, (CCPA 1973).

6. Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

7. In the response of 18 May 2006 applicant's representative asserts that the decision of *Raible* is inappropriate as no issue of 35 USC 112, first paragraph, exists. This argument has not been found persuasive as the amendment of 18 May 2006 is deemed to comprise new matter. Accordingly, the issue of support for newly added claims and their limitations is at issue.

Claim Rejections - 35 USC § 112

8. Claims 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly added claims 21-28 are deemed to constitute new matter as support for the newly added claims was not specifically identified by applicant's representative and a review of the disclosure fails to identify same. Accordingly, and in the absence of convincing evidence to the contrary, and in the absence of convincing evidence to the contrary, claims 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,849,486 (Heller et al.) in view of US Patent 5,607,646 (Okano et al.).

12. Claims 10-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,849,486 (Heller et al.) in view of US Patent 5,607,646 (Okano et al.).

13. For convenience, claim 10, the sole independent claim pending, is reproduced below.

10. **(Original)** A method for isolating one or more different-sequence polynucleotides from a mixture, the method comprising:

- (a) flowing the mixture through a flow path containing a plurality of solid supports which are located in series in the flow path, each support having bound thereto a sequence-specific capture agent complementary to a different-sequence polynucleotide, under conditions effective to specifically bind different-sequence polynucleotides to corresponding sequence-specific capture agents on one or more of the supports,
- (b) after said specific binding, releasing bound polynucleotides from a selected support by altering a physical property of that support while leaving unaltered the same physical property of at least one other of the supports,
- (c) eluting the released polynucleotides through the flow path such that the eluted polynucleotides can be isolated in separated form.

14. For purposes of examination claim 10 has been interpreted as encompassing the isolation of from one to an infinite number of nucleic acid sequences, and that at a minimum, two different capture moieties are to be present and are bound at two different locations on a support that can virtually any shape but can act as a flow path for a mixture of nucleic acids capable of flowing.

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15. Heller et al., (abstract) disclose a method whereby a fluidic system is used to isolate one or more different polynucleotide from a mixture. The method calls for the flowing of a sample across reactive members of a biochip. To facilitate the isolation and selective binding of the polynucleotide(s) to their most specific capture agents, one modifies various physical properties. In one instance, the electric field is manipulated. At column 5 Heller et al., disclose “each individual micro-location is able to control electronically and direct the transport and attachment of specific binding entities (e.g., nucleic acids, enzymes, antibodies) to itself. All micro-locations can be addressed with their specific binding entities.

16. Column 11, second paragraph, Heller et al., teach “Specific analytes or reaction products may be released from any microlocation 26 and transported to other locations for further analysis; or stored at other addressable locations; or removed completely from the system.”

17. While Heller et al., do teach altering the electric field so to increase stringency of binding reaction, they do not teach specifically of there being a change in heat.

18. Okano et al., column 2, bridging to column 3, like Heller et al., teaches using a biochip, binding nucleic acids to specific areas, and selectively removing polynucleotides as a result of altering the electric field. However, at column 3, last paragraph, Okano et al., teaches specifically of there being an increase in temperature which facilitates the separation of captured polynucleotides from the binding moiety.

19. Okano et al., abstract, teaches, “On the reaction chip are arranged a plurality of independent cells for capturing different target polynucleotides...[and that] different probes are immobilized onto the individual cells.” Such speaks directly to there being a plurality of

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supports. Okano et al., column 9, also teaches explicitly of one using lambda Hind III fragments (a nucleic acid ladder)

20. In view of the combined teachings of Heller et al., and Okano et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the methods of Heller and Okano et al., so to achieve in producing a method of isolating polynucleotides where said polynucleotides flow along a flow path, bind to a sequence-specific capture reagent, and are eluted through the flow path in separated form, wherein said elution is achieved through the modification of a physical property, including, voltage and heat. In view of the detailed teachings, reproducibility of the method, said ordinary artisan would have had a most reasonable expectation of success in applying this method to polynucleotides produced by various methods, as it is well settled that a compound and its properties are inseparable.

21. For the above reasons, and in the absence of convincing evidence to the contrary, claims 10-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,849,486 (Heller et al.) in view of US Patent 5,607,646 (Okano et al.).

Response to argument

22. At page 6 of the response received 18 May 2006 argument is presented that the prior art of record does not teach using a plurality of solid supports and that the conditions at one site can be altered without changing the conditions at another such site.

23. The above argument has been fully considered and has not been found persuasive for upon review of Heller et al., at Figure 2A, and the description of same found at column 20, elements 16A-16D are independent "attachment layers" to which a nucleic acid binds. Further, the ability to alter the charge of a single electrode independently of others (Fig. 2B), speaks

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directly to one being able to alter the conditions of one site without altering the same physical property of at least one of the other supports.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

25. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS